

REMARKS

The present application is divisional of U.S. Patent Application No. 10/008,788, filed December 7, 2001, which is a reissue of U.S. Patent Application No. 08/985,840, filed December 5, 1997, now U.S. Patent No. 5,997,817, as issued with original claims 1-32.

During prosecution of U.S. Patent Application No. 10/008,788, a restriction requirement was issued under 35 U.S.C. §121 requiring an election between a first invention grouping including original issued claims 1-32 from U.S. Patent No. 5,997,817, and a second invention grouping including newly added claims 39-67. The first invention grouping including claims 1-32 was asserted to be constructively elected and the second invention grouping including claims 39-67 was withdrawn from consideration by the Examiner. Original claim 1-32 were indicated as being allowable, while claims 39-67 were held in abeyance in a withdrawn status pending examination of new claims 39-67 in a divisional reissue application. To that end, the Applicant hereby submits new claims 39-67 for examination in the subject reissue divisional application.

Specification

The Applicant has amended the first page of the Specification to reflect the updated priority data associated with the subject application.

Claims

The Applicant has cancelled claims 1-38 without prejudice and reserves the right to pursue those or other claims in a subsequently filed application. Additionally, the Applicant has submitted new claims 39-67 which were previously presented in U.S. Patent Application No. 10/008,788. The Applicant has appended to this amendment a table showing the current status of the claims and citations to the specification that support the subject matter recited in the new claims 39-67.

The Applicant submits that pending claims 39-67 are believed to be patentable over the art of record. Claims 39-67 are directed to the concept set forth in the application pertaining to the ability to follow the flow of fluid, typically blood, as it enters a test strip. As noted in the pending claims, the test strip is of a type that is filled from an edge and the

progress of the fluid can be viewed from the entry port up to a “fill line” that indicates that a sufficient amount of fluid has been received for testing purposes. This provides several distinct advantages for the user. For example, the ability to view the fluid flow is an immediate confirmation that the fluid has been properly dosed to the entry port. The visualization of the fluid flow also provides direct feedback that the test strip is functioning properly to allow the fluid to wick into the strip, as by capillary action. The time it takes for the fluid to flow, and any irregularities in the movement of the fluid, will also provide indications of whether the test strip appears to be functioning appropriately. Finally, the success of the fluid in reaching the fill line will provide direct confirmation that the amount of fluid received within a test strip is sufficient to conduct a reliable test. It may even be possible for a user to quickly dose additional amounts of fluid to the test strip to make up for an inadequate initial supply of fluid, thereby avoiding having to use another test strip.

The primary reference previously cited against cancelled claims 33-38 in U.S. Patent Application No. 10/008,788 was U.S. Patent No. 6,027,692 to Galen et al. (hereafter “the Galen patent”). The Galen patent describes a top loading test strip in which a fluid sample is applied through a hole 6 in the top support 1. The sample may pass through holes 7 in intermediate layers 2, 3 and/or 4, and through blood separation layers 9 and buffer pad 13 to indicator (dye) pad 14. The test reaction at the dye pad 14 can then be detected at the underside at bottom support 5. The Galen patent describes that the bottom support may be, e.g., transparent such that the optical detection can occur through the support, or alternatively a hole may be provided if the bottom support is opaque. The Galen patent therefore does teach that a sample may be optically accessible at a point where the reaction occurs, as is inherent in an optical test strip. However, the Galen patent does not teach the visualization of the fluid flow to provide feedback as to the progress and sufficiency of the fluid. Further, the Galen patent does not describe or suggest an edge fill test strip in which the fluid flow is visible as it moves laterally through a capillary fill chamber to a fill-to-here line which indicates that a sufficient amount of fluid has been received for testing purposes.

The specification variously describes the nature and function of the test strip with regard to the monitoring of the filling of the capillary chamber in the inventive test strip. In one sense, the test strip provides a “fill line” that provides a direct, visual confirmation that a sufficient amount of fluid has been received by the test strip. For example, claim 39 recites

that:

“the filling of liquid to the fill line indicates sufficient filling of the capillary test chamber for the test strip to be useful in testing the bodily fluid.”

In correspondence to this language, the specification (with references to the patent text) indicates that the strip includes “a transparent or translucent window that operates as a ‘fill to here’ line, thereby identifying when enough test sample . . . has been added to the test chamber to accurately perform a test.” Column 1, lines 63-67. Similarly, at column 1, line 67 to column 2, line 4, it is indicated that the strip “represents a visual failsafe which reduces the chances of erroneous test results due to underdosing of a test strip.” At column 8, lines 61-67, the specification further states that the strip provides “feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample.”

It is therefore apparent that the present claims readily distinguish over the Galen patent. The claimed invention relates to an edge fill device in which the entering fluid is visualized as it moves toward a fill line, and that fill line provides direct feedback to the user that a sufficient amount of fluid has been dosed to the test strip for it to be useful in testing the fluid.

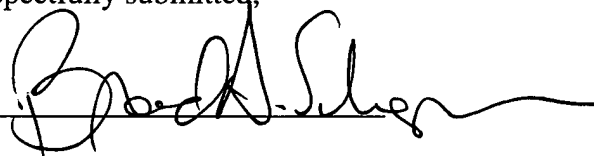
The case now includes three independent claims 39, 56 and 61 directed to various aspects of this concept. For example, claim 39 refers to a test strip that includes an opaque portion and a transparent or translucent portion which both overlie the capillary test chamber and together define a fill line extending across the capillary test chamber, the progress of liquid to the fill line indicating sufficient fluid for conducting a test. Claim 56 covers a test strip having a transparent or translucent portion overlying the capillary test chamber and an opaque fill line positioned to indicate sufficient filling of the capillary test chamber. Claim 61 applies to a test strip having a transparent or translucent portion and an opaque portion together defining a fill line that indicates a sufficient amount of fluid to accurately perform a test. All of these claims, and therefore the claims dependent thereon, are patentably distinguishable over the cited references based upon these elements, and further in providing a test strip that has an edge fill chamber covered with a transparent or translucent portion through which the movement of the fluid into and through the capillary test chamber can be visualized.

The claims are also distinguishable based on other features. Claim 1, for example, requires that the fill line is positioned intermediate the length of the capillary test chamber. Claims 42, 57 and 62 provide that the transparent or translucent portion extends inwardly from the sample application port. Claims 46, 58 and 63 state that the test strip includes a vent hole, and claims 47, 59 and 64 provide that the fill line is positioned between the sample application port and the vent hole. These and other features contained throughout the claims provide further patentable distinctions over the cited art, including specifically the Galen patent.

For at least the foregoing reasons, the Applicant submits that pending claims 39-67 are patentable over the prior art, and allowance of the subject application is respectfully requested. If the Examiner believes there are any outstanding matters that can be addressed in a telephonic interview, the undersigned would welcome such an interview.

Respectfully submitted,

By



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